

Award Number: W81XWH-11-2-0222

TITLE: The BADER Consortium

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REPORT DATE: October 2012

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 31-October-2012		2. REPORT TYPE Annual Report		3. DATES COVERED 30 September 2011- 29 September 2012	
4. TITLE AND SUBTITLE The BADER Consortium				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-2-0222	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Steven J. Stanhope, PhD E-Mail: stanhope@udel.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Delaware Newark, Delaware 19716				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT- The overarching goal of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior. Over the five-year award period, this will be accomplished by focusing on a MTF centric approach that will advance each of the following strategic areas: 1: INFRASTRUCTURES: Assist each MTF with strengthening a research-intensive culture 2: PARTNERSHIPS: Work to fully realize a robust orthopaedic rehabilitation research partnership across MTF and non-MTF clinical research sites 3: RESEARCH: Support MTF goals of conducting a variety of high impact research studies 4: SUSTAINMENT: Assist MTFs with the establishment of their self-sustaining research enterprises. Key Accomplishments year 1: Established Administrative Core, Clinical Research Core and Scientific Technical Core; Approval and establishment of two clinical research projects; HRPO clearance and start of first project; Initiated the development of first IRB of record outside the MTFs; Development and implementation of an Omnibus CRADA; Established a consortium-wide PDMS; Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE); Worked with the EACE to develop research focus (gap) areas for BADER Consortium's call for proposals; Established and implemented a complete process for the call, submission, review and selection of Consortium funded projects; Published the BADER Consortium call for clinical research proposals Established the BADER Consortium SOPs; Initiated the hiring of eight research support staff to be placed onsite at MTFs; Established partnerships with the VA and NIH					
15. SUBJECT TERMS- Orthopaedic, rehabilitation, research					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
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BADER CONSORTIUM

ANNUAL



REPORT



THE BADER CONSORTIUM

ANNUAL REPORT

FOR THE PERIOD

09/29/2011-09/28/2012

W81XWH-11-2-0222

Funding provided by the Congressionally Directed Medical Research Programs, Peer Reviewed Orthopaedic Rehabilitation Program (PRORP)

Orthopaedic Rehabilitation Clinical Consortium Award

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Letter from the Director of the Consortium

This is an extraordinary time for orthopaedic rehabilitation research and patient care. By establishing the Extremity Trauma and Amputation Center of Excellence (EACE) and the BADER Consortium, the U.S. Congress, Department of Defense (DoD) and Department of Veterans Affairs (VA) have forever altered the course of orthopaedic rehabilitative care for wounded warriors.

Soldiers are surviving severe traumas with significant limb injuries and limb losses that historically lead to significant disabilities and burden of care. With the establishment of the BADER Consortium in October of 2011, expectations for orthopaedic rehabilitation outcomes have been set at a challenging new level. Obtaining the highest level of function is the BADER Consortium's desired outcome of care for every wounded warrior with traumatic orthopaedic injury; as such, the Department of Defense's Congressionally Directed Medical Research Programs (CDMRP), is further challenging the clinical community, federal agencies, industry and academia to unite and make lasting transformations in the lives of wounded warriors.

The overarching goal of the BADER Consortium is to return wounded warriors to "optimal" levels of function. Our objective is to establish new evidence-based care practices through the formation of a nationwide clinical research enterprise, for partnering, translation of advanced rehabilitation technologies and the conduct of impactful clinical orthopaedic rehabilitation research.

To realize Department of Defense goals, BADER Consortium staff and affiliates spent much of the first year developing research infrastructures in support of the EACE. These infrastructures streamline the rapid execution of clinical studies involving military and non-military clinical research centers, academia, industry and an array of federal agencies. Our efforts have successfully developed and implemented an unprecedented pathway for translating advanced orthopaedic rehabilitation technologies into clinical studies and the establishment of new evidence-based patient care practices.

This annual report contains numerous highlights from our first year of discovery and establishment. First, you will see that we have two multi-site clinical projects already underway. You will also find that we've made tremendous progress reaching and exceeding the majority of our first year goals, and we can point to major successes in each of our key areas.

This upcoming year is expected to be a very special year for the BADER Consortium. Our limited competition research proposal awards program is well underway. Multiple teams are hard at work developing clinical research proposals for submission to the BADER Consortium Research Advisory Committee. Consortium research support staff will soon be joining medical treatment facilities throughout the country. Our omnibus Cooperative Research and Development Agreement and Protocol and Data Management System will both be fully implemented across the Consortium and, we eagerly anticipate participating in the first annual BADER Consortium Orthopaedic Rehabilitation meeting.

We are honored to be partnering with a rapidly growing community of orthopaedic rehabilitation experts to help our wounded warriors reach their personal goals and live rich and empowered lives. Please follow our progress and consider joining our Consortium of partners in achieving our common goal of obtaining optimal functional recovery for each and every wounded warrior.

Steven J. Stanhope
Director, BADER Consortium

About the BADER Consortium

BADER is an acronym for “Bridging Advanced Developments for Exceptional Rehabilitation.” Typifying exceptional function following injury, Royal Air Force fighter pilot Sir Douglas Bader lost both legs in a plane crash but went on to shoot down 22 German planes and attempt multiple escapes as a POW during World War II.

Led by the University of Delaware, the BADER Consortium is initially partnering with four Department of Defense Medical Treatment Facilities to advance evidence-based orthopaedic rehabilitation for wounded warriors so that each patient can reach his or her optimal level of function.

The BADER Consortium initially brings together researchers, health professionals and physicians from the University of Delaware; Spaulding Rehabilitation Hospital; Harvard Medical School; the University of Texas at Austin; Christiana Care Health System; the Mayo Clinic; the Naval Medical Center in Portsmouth, Va.; the Naval Medical Center in San Diego; San Antonio Military Medical Center; Walter Reed National Military Medical Center; C-Motion Inc. in Germantown, Md.; and the University of Michigan.

Funding for this Orthopaedic Rehabilitation Clinical Consortium Award (ORCCA) is provided by the United States Department of Defense’s Office of Congressionally Directed Medical Research Program through its Peer Reviewed Orthopaedic Rehabilitation Program.

Executive summary

The **overarching goal** of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.

Over the five-year award period, this will be accomplished by focusing on a Medical Treatment Facility centric approach that will advance each of the following strategic areas:

- 1) **INFRASTRUCTURES:** Assist each MTF with strengthening a research-intensive culture
- 2) **PARTNERSHIPS:** Work to fully realize a robust orthopaedic rehabilitation research partnership across MTF and non-MTF clinical research sites
- 3) **RESEARCH:** Support MTF goals of conducting a variety of high impact research studies
- 4) **SUSTAINMENT:** Assist MTFs with the establishment of their self-sustaining research enterprises

To meet these goals, cores have been established to provide the necessary expertise in the following areas:

Administrative Core:

Purpose: To bring together the personnel and resources to ensure that the goals of the BADER Consortium are achieved in the areas of Partnership, Finance, Human Resources, Reporting, Policies and Procedures, Compliance, Legal, IP, Training, Information Technology.

Clinical Research Core:

Purpose: To further develop and support a research-intensive culture in the MTFs by assisting the MTFs with establishing a uniform and sustainable research infrastructure that will facilitate ongoing and new MTF clinical research protocols across all sites.

Scientific Technical Cores:

Purpose: To support multi-site MTF clinical studies by providing additional scientific infrastructures and resources (Biostatistics, Outcomes Measurement and Biomechanics) for the conduct of impactful clinical orthopaedic rehabilitation research.

Key Accomplishments in the first year of performance:

- Approval and establishment of two clinical research projects
- HRPO clearance and start of first project (Dingwell)
- Initiated the development of first IRB of record outside the MTFs (Davis)
- Initiated the development of partnership with Nike, USA (Davis)
- Development and implementation of an Omnibus Cooperative Research and Development Agreement (CRADA)
- Established a consortium-wide protocol and data management system
- Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE)
- Worked with the EACE to develop research focus (gap) areas for the BADER Consortium call for proposals
- Established a complete process for the call, submission, review and selection of Consortium funded projects
- Published the BADER Consortium call for clinical research proposals
- Established the BADER Consortium web site and standard operating procedures (SOPs)
- Initiated the hiring of eight research support staff to be placed onsite at MTFs.
- Open communication with all MTFs and partners through bi-weekly teleconferences
- Established partnerships with the VA and NIH

Introduction

The nature of war-time injuries has changed dramatically over the course of the past twelve years as a result of increased technology on the battlefield and as a result of America's experience in Iraq and Afghanistan. Thanks to rapid mobile medicine and improved body armor technology, soldiers now regularly survive events that would have proved fatal in previous conflicts. Soldiers who sustained injuries in World War II had a 69 percent survival rate. Wounded soldiers in the Korean War had a 75 percent survival rate and soldiers in the Vietnam War had an 86 percent survival rate. Thanks to technology development, soldiers wounded in Operations Enduring Freedom and Iraqi Freedom have a remarkable survival rate of nearly 95 percent.

At the same time, these survival rates have been accompanied by new challenges in rehabilitation and changing attitudes about what it means to be a wounded warrior. While in past generations severely wounded soldiers would be immediately retired from service, new attitudes about capabilities and recovery and advanced rehabilitation technologies are beginning to allow alternative outcomes for soldiers with multiple amputations. Wounded soldiers today often seek to return to service as a result of their commitment to the military and their country, and as many have chosen the military as a career and want to continue to pursue their work and dreams.

Additional challenges have resulted from an ever-changing battlefield. The use of improvised explosive devices (IEDs) and high velocity weapons in Iraq and Afghanistan has resulted in new forms of injury and rehabilitation once considered rare among returning wounded soldiers. These changes have occurred at the same time as dramatic advancements in the development of composite materials and prosthetic technology.

Partners

Obtaining the highest level of function is now the desired outcome of care for every wounded warrior with traumatic orthopaedic injury; as such, the Department of Defense is currently challenging the clinical community, industry and academia to unite and make lasting transformations in the lives of wounded warriors.



To realize this desired outcome, the BADER Consortium is developing research infrastructures that will allow for rapid execution of clinical studies involving military and non-military clinical research centers, academia and industry, and ultimately establishing evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for wounded warriors.

A key component of achieving this mission is the establishment of strong, strategic and sustainable partnerships. Essential to this will be the implementation of communication efforts to promote the BADER Consortium's mission, create awareness of opportunities to participate and to foster collaborations. Strategic partnerships developed in the first year of performance are included in the following table.

Federal Government	Academic	Industry	Non-Profit
Brooke Army Medical Center – Center for the Intrepid	Harvard University	Ossur	Amputee Coalition
Naval Medical Center Portsmouth	Spaulding Rehabilitation Hospital	Otto-Bock	Mid-Atlantic Agrability
Naval Medical Center San Diego	The Mayo Clinic	Independence Prosthetics and Orthotics	Christiana Care Health Systems
Walter Reed National Military Medical Center	University of Texas – Austin	C-Motion, Inc	
Department of Veteran's Affairs	University of Michigan	iWalk	
National Institutes of Health		Hanger	
		Nike, USA	
		Simbex	

Overview: Year 1 Progress toward Strategic Focus Areas

The BADER Consortium has made notable progress to date over the first year of performance toward the following key concepts: Infrastructures, Partnerships, Research and Sustainability. This report will indicate significant steps have occurred in each of our focus areas:

- 1) Infrastructure: Assist each MTF with strengthening a research-intensive culture
- 2) Partnership: Work in concert with MTFs to fully realize a robust orthopaedic rehabilitation research partnership across MTF and non-MTF clinical research sites
- 3) Research: Support MTF goals of conducting a variety of high impact research studies
- 4) Sustainment: Assist MTFs with the establishment of their self-sustaining research enterprises

In total, this indicates a highly effective and concerted effort under this initial “Discovery and Establishment” phase. The following summarizes several of the highlights in each strategic area.

- 1: Infrastructure: Assist each MTF with strengthening a research-intensive culture by establishing key infrastructures
 - a. Established the Administrative Core to provide support in the following areas:
 - i. Recruitment of Personnel
 - ii. Finance and Budget
 - iii. Standard Operating Procedures
 - iv. Cooperative Research and Development Agreements
 - v. Communications
 - b. Established the Clinical Research Core
 - i. Led the effort to fully vet the Consortium-wide Protocol and Data Management System (PDMS)
 - ii. Worked closely with MTF leadership in recruitment of Consortium funded research personnel
 - c. Established the Scientific Technical Core
 - i. Developed policies and procedures
 - ii. Conducted site visits
 - iii. Developed key infrastructures to support research protocols
 - d. MTF representatives have been thoroughly briefed on the nature, intent and implementation steps of the BADER Consortium and the process of defining individual as well as a united vision of a research intensive culture is fully underway.
 - e. MTF and BADER Consortium leadership worked collectively to share and develop model staffing plans that incorporate BADER Consortium, EACE, and existing MTF resources. Using these model staffing plans:
 - i. Supported establishment of onsite research expertise by:
 1. Initiated recruitment activity for each MTF to have BADER Consortium sponsored on-site, Protocol Managers and Research Assistants.
 2. Initiated the process of recruiting MTF staff to the BADER Consortium Affiliate pool.
 3. Formalized procedures for awarding scholarships to the University Biomechanics and Movement Science (BIOMS) graduate program.
 4. Partnered with each MTF to develop position descriptions for their BADER Consortium sponsored on-site Protocol Managers and Research Assistants.
 - f. Several milestones were passed with our efforts to establish a trans-institution clinical research and tissue data repository enterprise system.

- i. A team of BADER Consortium Affiliates, including representatives from each military MTF, approved the path forward on fully vetting the consortium Protocol and Data Management System (PDMS).
- ii. An ad-hoc committee consisting of MTF and University of Delaware information technology (IT) specialists completed discovery of the list of PDMS implementation specifications related to IT infrastructure and information security requirements.
- iii. The University of Delaware Vice-President for Information Technology approved support for the BADER IT infrastructures, committing to meet or exceed all DoD implementation requirements.

2. Partnership: Work in concert with MTFs to fully realize a robust orthopaedic rehabilitation research partnership across MTF and non-MTF clinical research sites

- a. Multiple site visits have occurred across the MTFs. The site visits have engaged a full range of personnel including: research, clinical, administrative, IT, IP staff with BADER Consortium Leadership and Scientific Core personnel.
- b. MTF representatives and BADER Consortium personnel have established and implemented a plan to conduct regular group meetings as a united team.
- c. The Biomechanics Core provided essential support for the execution of a multi-site CRSR project geared to compare human movement data across MTF sites.
- d. As a key communication tool, the BADER Consortium web site has gone live.
- e. A multi-account, BADER Consortium teleconference system has been established and implemented across MTF and collaborating sites.
- f. MTFs are considering uniformly implementing a novel (Unified Deformable Segment) method we developed for measuring combined ankle and foot biomechanics.
- g. Worked in partnership with MTF representatives to develop the position description and initiate recruitment of the consortium-wide Manager of the Clinical Research Core
- h. Bi-weekly meetings of the BADER Consortium Committee (BCC) are underway to strengthen the lines of communication between the BADER Consortium and the MTFs.
- i. The BADER Consortium has joined forces with the Extremity Trauma and Amputation Center of Excellence (EACE)
- j. Initiated Consortium wide use of the Defense Connect Online (DCO) system.
- k. Initiated outreach to the VA.

3. Research: Support MTF goals of conducting a variety of high impact research studies

- a. Real and effective MTF partnerships have been established for two of the four initially proposed BADER Consortium research projects.
- b. Several MTFs are actively exploring project concepts for submission to the first round of competed BADER Consortium proposal submissions.
- c. Project 2012.2 – “Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback” has been approved by the Government Steering Committee (GSC) and Dr. Davis is moving forward with IRB approvals to have this project up and running by November 15, 2012.

Project 2012.1 – “Improving Step-To-Step Control of Walking in Traumatic Amputees” under the leadership of Dr. Jonathan Dingwell received GSC approval and has received all IRB and HRPO approvals for a September 1, 2012 start date.

- d. The call for proposals (projected start dates 10/1/2013) was released to BADER Consortium Affiliates in mid-September.

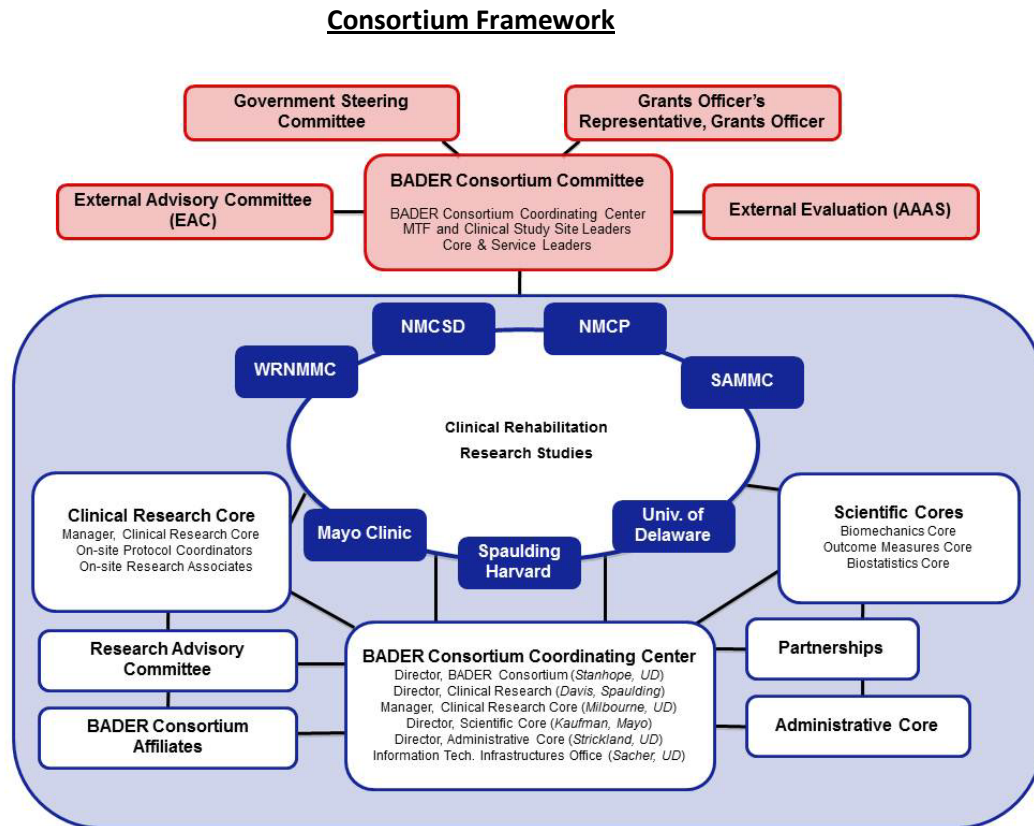
- e. The BADER Consortium has provided support for a Center for Rehabilitative Sciences Research (CRSR) project through the Biomechanics Core.
- f. Successful recruitment of a well-qualified Manager of the Clinical Research Core to oversee BADER Consortium Clinical Research Core support activities.

4. Sustainment: Assist MTFs with the establishment of their self-sustaining research enterprises

- a. External funds have begun to bolster BADER Consortium/ MTF priority research areas and activities.
 - i. \$3M DARPA grant awarded for the rapid manufacture of composite orthoses for wounded warriors. (UD – Gillespie, Stanhope)
 - ii. NIH SBIR Phase I submission for development of an advanced treadmill training feedback system has been awarded to C-Motion, Inc to support the Davis “Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback” protocol (C-Motion, inc. Selbie)
 - iii. The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.
 - iv. The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.
 - v. Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD project and plans to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.
- b. Protocol and Data Management System (PDMS) – significant progress made in working toward implementation of a PDMS. Anticipated rollout November 2012.
- c. BADER Consortium website development continues:
 - i. Secure log-in development complete
 - ii. Call for proposals web forms complete
 - iii. Expanded partnership component
 - iv. Research resources routinely added

Phase I – Discovery and Establishment – Developing Consortium Infrastructures

A primary focus in year 1 was building strong, efficient and sustainable administrative infrastructures to provide the best level of service over the next four years enabling scientists to focus on the research.



The Administrative Core

If developing a research cooperation between a civilian organization and a government agency is considered by most to be a challenging endeavor, establishing an effective and dynamic research Consortium across multiple agencies, academic centers, and industrial leaders would be considered daunting. To tackle this task, the BADER Consortium has established a series of model administrative tools and standard operating procedures. Fundamentally, these tools and associated policies and procedures ensure protection of critical assets such as: the US Governments rights to intellectual property and data, patient confidentiality, and human subjects.

Model Cooperative Research and Development Agreement

A common delay in conducting research is negotiating the Cooperative Research and Development Agreement (CRADA) between agencies and other research entities. In an effort to reduce this administrative delay, members of the Administrative Core developed a model omnibus CRADA to streamline the CRADA approval process. This model CRADA creates a standard operating procedure that addresses intellectual property, publications, data sharing, subject inventions and licensing among all CRADA activities. The model CRADA is a unique procedure which allows the

Consortium to rapidly ‘onboard’ individual entities into a single omnibus CRADA with the University of Delaware that covers general BADER Consortium activities. Activities associated with specific research projects use the same CRADA mechanism by adding details of the research project and partners as an addendum. With support and guidance from the Chief, Medical Research Law, Office of the Staff Judge Advocate, U.S. Army Medical Research and Materiel Command, the CRADA was finalized and distributed to all current partner organizations in early September 2012. With the streamlined nature of the model CRADA, at this time, we have successfully on-boarded three entities to the model CRADA with several more to be fully executed in the first month of the second year of performance.

Standard Operating Procedures

Every organization relies on Standard Operating Procedures (SOPs) in order to improve efficiency, be in compliance with regulations and apply policy consistently across the Consortium. The SOPs for the BADER Consortium were established in 2012 and will be considered a living document – to be reviewed annually and as necessary to be in compliance with Federal, State and University regulations and to adapt to a changing environment. The comprehensive document includes policy and procedure in the following areas:

- Governance
- Research Study Initiation and Implementation
- Data Management and Data Collection
- Quality Assurance and Quality Improvement
- Study Management and Monitoring
- Publications and Presentations
- Cooperative Research and Development Activities
- Clinical Site Performance
- Fiscal Management
- General administrative

Principal Investigator Onboarding process

A rapid research implementation standard operating procedure has been developed that supports Consortium investigator efforts to ramp up research protocol operations quickly, even if all IRB and mandatory HRPO approvals have not been received. By executing the Principal Investigator (PI) Researcher Agreement, the Consortium is able to issue a conditional subcontract which allows the PI to recruit research personnel, order equipment and supplies and begin research that does not involve Human Subjects. This allows the PI to fully prepare to execute the protocol while awaiting final IRB/HRPO approvals. Once all IRB and final HRPO approvals are received, the PI receives a letter from the Consortium giving approval to move forward with human subject recruitment.

Staffing support for MTF research programs

Establishing key research infrastructures at MTFs in the form of research and research support staff is a priority for EACE and the BADER Consortium. Over the course of the first year of the Consortium, key management team positions were filled. A full-time Director of the Administrative Core and a Manager of the Clinical Research Core were both recruited with talented, experienced personnel.

Working closely with the MTF representatives and in full cooperation with EACE staffing efforts, on-site personnel needs at each of the MTFs were identified and recruitment activity was initiated. As proposed and budgeted, each of the four MTFs will be supported by a Research Associate and a Protocol Coordinator. These essential positions provide critical

research infrastructure support for the MTF research staff and clinical collaborators. We anticipate having all eight positions filled and stationed on site at each MTF by the end of calendar year 2012.

Facilitating Communications

Easy and quick access to information and support is essential. The Administrative Core has worked diligently over the first year to establish tools to allow researchers and administrative staff to communicate effectively, efficiently and without delay.

Website development

The BADER Consortium website (bader-c.org) was officially launched during the first quarter of performance and evolved significantly over the course of the first year. As a key communication tool, the website currently includes information about the Consortium, forms for reporting, partners currently identified, services provided by the Scientific Technical Cores and news related to the launch of the Consortium. A secure log-in is available for BADER Consortium Affiliates to access Call for Proposal materials as well as SOPs and Consortium reports and forms.

Communication/Video Conference capabilities

Communication among all BADER Consortium community members is vital to efficient and effective implementation of large-scale rehabilitation research projects enabled through the BADER Consortium. Key determinants for choosing appropriate technologies include the need for secure communications, video/audio quality, content-sharing, recording and playback, ease-of-use and ease-of-support. With the following options, we have created low-cost, highly-effective communication tools to join geographically diverse entities.

Real-time video collaboration: Meeting security requirements of DoD sites and civilian clinical sites is the single biggest hurdle to video and screen-sharing among all Consortium sites. With the helpful assistance of DoD's IT staff, we've been able to converge to a set of software and hardware solutions that will meet all parties' needs with low impact on each site's staff.

Additional testing among sites is still needed, but we are optimistic that our current planned implementation will be very successful. It is based around three types of situations: webinars, ad hoc videoconferences with fewer than three participating sites, larger multi-site videoconferences such as for annual meetings.

Webinars will be enabled by Adobe Connect, or the DoD secure-equivalent, Defense Connect Online system.

Videoconferencing will use free or low-cost software (CISCO's Jabber/Movi, Logitech Softphone). DoD's USAMITC gatekeeper services will provide DD participants additional security. Where needed, we'll purchase Logitech ConferenceCams to provide small conference-room HD-video and speakerphone capabilities. Large flat-panel displays may complement other HD-quality displays. The University of Delaware will provide CISCO-based video-bridging services for videoconferences involving more than three sites. In all cases, meetings can be recorded and made available for playback.

The University of Delaware has established three teleconference phone accounts that are available for use by all Consortium members.

Announcement of Education Scholarships

Through the BADER Consortium, the University of Delaware is committed to furthering the education of future researchers by providing \$1.2 million in tuition scholarships to qualified individuals who are interested in pursuing an advanced degree in Biomechanics and Movement Science. These individuals will be trained as the next generation of biomechanics researchers to further enhance the scientific talent at the Medical Treatment Facilities.

BADER Consortium Affiliates

A major eligibility criterion to receiving Consortium support for research projects and Core support is being a BADER Consortium Affiliate (BCA). In the initial proposal phase as well as over the first year, leadership in the Consortium and MTFs identified the first 40 BCAs. Over the next year, the intent is to further strengthen that pool.

A BADER Consortium Affiliate is an expert in an area of orthopaedic rehabilitation care, research, technology, or administration who is permitted to engage the BADER Consortium in the identification, planning and execution of impactful orthopaedic rehabilitation scientific studies and investigations using BADER Consortium resources. In addition, BCAs may help to promote orthopaedic rehabilitation research at each Military Treatment Facility by mentoring emerging scientists. BCAs may also assist with sustaining the BADER Consortium by conducting externally funded and BADER Consortium affiliated projects. BCAs will have access to BADER Consortium information and communication resources and are encouraged to engage the BADER Consortium to establish lasting orthopaedic rehabilitation research partnerships.

Once accepted as an Affiliate the BCA will qualify to:

- participate in the BADER Consortium research project program and qualify to receive BADER Consortium research support;
- receive services provided by the BADER Consortium Scientific Technical Cores;
- access Consortium website secured materials and receive limited distribution program announcements;

Annual meeting

Plans are underway to hold an annual orthopaedic rehabilitation meeting sponsored by the BADER Consortium and key strategic partners. The proposed annual meeting will address both the business and scientific aspects of the BADER Consortium. Approximately 50% of the meeting will focus on scientific presentations. Principal Investigators receiving research support from the BADER Consortium will be asked to provide updates on their project status. The goal of this meeting will be to further coordinate research efforts by supporting communication and networking among the orthopaedic rehabilitation community at large, Consortium investigators and administrative leaders of the BADER Consortium. The business aspect of the meeting will cover the following key areas:

- Update on BADER Consortium
- Executive Committee reports
- Scientific Core reports
- Establish current of standards for O & P measurements and standardization of data collection procedures
- Formation and operation of clinical trials
- Intellectual property
- Sustainability
- Cooperation and integration between the BADER Consortium and the EACE
- Establishment of yearly priorities

The annual meeting will be held at one of the MTFs each year. The location will rotate across all the MTFs. This will give an opportunity for the clinicians at each MTF to participate in person, learn about the BADER Consortium, and help guide the translational aspects of the ongoing research to achieve optimal functional outcomes. In addition to the local clinicians, attendees will include Principal Investigators of all research projects, members of the BADER Consortium Coordinating Committee, External Advisory Committee, and individuals from CDMRP. The BADER Consortium Administrative Core has begun developing plans for establishing virtual meeting capabilities that will support remote participation in all aspects of the meeting. The meeting will be held in an April to May timeframe so that research gaps may be identified for the Call for Proposals which will be released in August of each year. Look for an opportunity to join the annual meeting planning team.

The Clinical Research Core

Protocol and Data Management System - data management/storage/reporting functions

An important BADER Consortium investment is the development of a sustainable and highly productive research program. A key element is the implementation of a Consortium-wide data management plan and the application of methods to monitor quality and consistency of data collection. During project year 1, staffing needs and information technology (IT) infrastructures in support of a Consortium-wide research intensive culture were considered. The Research Core hired a Clinical Research Manager to manage the Clinical Research Core and oversee the training necessary to utilize the Protocol and Data Management System (PDMS) and apply methods to monitor quality and consistency of data collection.

Through a discovery process, the Consortium Clinical Research Core and IT support staff identified a unique opportunity to partner with a federal agency and deploy a PDMS equivalent to the earlier proposed commercial system yet at far less cost. This partnership is primed to result in a new, highly visible, impactful application of the system in a broad range of orthopaedic rehabilitation studies by Department of Defense and Veterans Administration investigators, as well as other scientists and clinicians. The programmatic strengths of the partners offer synergistic opportunities to accelerate the application of the system for extramural research and allows for funds to be diverted back into the pool of dollars slated for supporting research studies proposed to the Consortium.

Named the Clinical Trials Data Base (CTDB) and designed by the National Institutes of Health, National Institute for Child Health and Human Development (NICHD), the system provides all of the necessary data collection, management and reporting functions. The CTDB and its supporting infrastructure has the capacity for economical sustainability beyond the Consortium funding period. The Consortium's Military Treatment Facility partners vetted and approved use of the CTDB. The BADER Consortium implementation is modeled after the successful collaboration of NIH/NICHD and the Congressionally established Center for Neuroscience and Regenerative Medicine (CNRN).

The CTDB is a web-based application that supports secure data management for natural history and clinical trial research studies. It provides key features for protocol study design, data collection, biospecimen tracking, and reporting. Use of the CTDB will reduce redundant data management within the Consortium, reduce data-management training for researchers, enlarge patient registries for future protocols, comply with broad federal-agency data-security requirements, increase ease-of-use leading to improved analysis, and assist with statutory report compliance.

The implementation approach may become a model for other federal and non-federal extramural partnerships with NICHD. We plan to host the system in the cloud at a secure hosting site offering managed hosting services. It will include an instance of the NIH/NICHD software, its supporting Oracle database, and IBM Cognos-based reports and ad hoc reporting tools. NICHD staff will assist with the initial installation and software maintenance. Staff associated with the hosting site will implement risk management controls required for the DIACAP/FISMA/NIST information security certification process. Cybersecurity consultants will assist with continuing monitoring required to maintain Authority to Operate (ATO) status. After completion of knowledge transfer between developers and Consortium staff, Consortium's staff tasked with data management will be able to develop case report forms for input and standard summary and subject histories for output. The overall process is governed by a Material Transfer Agreement and an NIH Collaboration Agreement with the University of Delaware on behalf of the Consortium.

Scientific Technical Cores

To further advance clinical research infrastructure, the Consortium has established three Scientific Technical Cores to provide researchers with resources that may not be readily available to them at a reduced cost or free through fee waivers.

Core Service	Core Director	Institution
Biomechanics	Scott Selbie, PhD	C-Motion, Inc
Biostatistics	Paul Kolm, PhD	Christiana Care Health Systems
Outcomes Measurement	David Tulskey, PhD	University of Michigan

These core services are available to Medical Treatment Facilities (MTFs) and also to BADER Consortium Affiliates during the development of a research proposal or while the research study is underway.

Key accomplishments of the Scientific Technical Cores over the first year of performance:

Biomechanics Core:

Site Visits: The Biomechanics team conducted site visits at three of the MTFs, gathering information on existing capabilities, feedback on anticipated needs, and a wish list of proposed enhancements to software and hardware systems.

Gait Retraining: Using non-BADER Consortium funding, C-Motion received a NIH SBIR Phase I award to develop biofeedback software. This software will be instrumental in Dr. Davis's "Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback" protocol.

Visual3D Version 5: Using feedback from the MTFs, improvements to the functionality of Visual3D are slated for the Version 5 release of Visual3D in October of 2012. The Version 5 release is critical to moving forward with new functionality for the MTFs.

Improvements to the CalTester: Based on testing conducted at Walter Reed National Military Medical Center it became clear that a more accurate method for locating force platforms within instrumented treadmills and stairs was needed before any BADER Consortium human subject testing should begin. This need was corroborated by the other MTFs. To move toward a solution, prototype software (CalTester+) was released for testing at Walter Reed and results were promising and efforts to implement a publically available version.

Biostatistics Core:

The Biostatistics Core is run as fee-for-service core.

During this initial year, core leadership developed the necessary policies and procedures related to accessing Core services.

The forms were developed for and currently reside on the BADER Consortium website.

The Biostatistics Core prepared to assist research teams with the development of project proposals in response to the BADER Consortium call for research project proposals.

Outcomes Measurement Core:

Built a measurement library and will work with the BADER Consortium technology team to develop a web-based library that would be accessible to all MTFs as part of the BADER Consortium web site.

Developed a review format for reports that will optimize both the usability of this resource and standardize the review process.

Identified an initial set of outcome measures that will be the first priority for uploading to the web-based measurement library.

Developing new targeted item banks for individuals with orthopaedic injuries and following HRPO approval will conduct focus groups at the MTFs.

- Received IRB approval to conduct an initial round of focus groups at the University of Michigan.
- Collaborated with Marilyn Wyatt at Naval Medical Center San Diego (NMCSD) to submit an IRB proposal to conduct focus groups at NMCSD and other MTFs.

Obtained electronic and hard-copies of freely-available instruments to aid accessibility of the measures to BADER Consortium researchers.

Developed an EndNote file that contains 169 pdf versions of source articles and articles that describe quality indicators (reliability, validity, sensitivity) for recommended outcome measures. This file will be made available to Consortium scientists through the BADER Consortium web site.

BADER Consortium Research

Phase II – Clinical Research Engagement

Consortium Funded Projects

Project 2012.1 – Improving Step-to-Step Control of Walking in Traumatic Amputees

PIs: Jonathan Dingwell, PhD and Jason Wilken, PhD

Clinical Research Sites: University of Texas, Austin and the Center for the Intrepid, Brooke Army Medical Center

Project dates: 01 September 2012 – 31 August 2015

Abstract: The objective of this study is to determine the step-to-step control strategies used by patients with lower extremity amputation and to develop a VR-based rehabilitation training program. Lower extremity amputees have high fall risk. To improve walking performance and to decrease falls and the injuries associated with falls in service members with lower extremity amputations. Program outcomes: Identify specific step-to-step control strategies and a new VR-based care paradigm.

Military relevance: Military amputees frequently participate in more demanding activities than most amputees. These activities may place them at greater risk of falling and further injury. This study addresses the military priority areas to “improve and enhance rehabilitative strategies for patients with severe limb trauma and amputation” by developing gait training interventions and evaluate amputee rehabilitation strategies to reduce long-term physical, personal and financial burdens associated with falls.

Key Accomplishments:

- IRB and HRPO approvals received for Aim 1 allowing research to begin in September 2012
- Subcontract from University of Delaware to University of Texas executed Aug. 31, 2012
- Subcontract from University of Texas to Penn State executed Oct. 4, 2012
- Post-doc hired and started work: Jonathan Rylander from Stanford University (Ph.D., Aug., 2012)
- University of Texas graduate research assistant already hired and started work: Mandy Salinas from University of Texas (Ph.D. started Sept., 2012)
- Data for Aim 1 analyses already available and processing is now starting.

Project 2012.2 – Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback

PIs: Irene Davis, PhD and Alison Linberg, DPT, ATC

Clinical Research Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center (WRNMMC)

Project dates: 29 September 2012 – 28 September 2014

Abstract: Lower extremity amputations significantly impact a soldier's gait function and their ability to return to active duty. Despite standard rehabilitative care that includes gait training, loading remains elevated in the intact extremity, increasing the risk for the development of degenerative joint disease. ***The purpose of this study is to examine whether symmetry of loading can be improved in both walking and running using real-time feedback in individuals with unilateral, transtibial amputations.***

Military relevance: Improve and enhance rehabilitation strategies for soldiers with amputations as measured by effectiveness and improvement of functional outcomes. Altering faulty gait patterns using the proposed techniques will help improve gait function and assist the wounded warrior to achieve their maximum overall function.

Key Accomplishments:

- Finalized research protocol
- The IRB materials have been submitted through Spaulding Rehabilitation Hospital/Harvard Medical School. Interagency Agreement with WRNMMC under development to recognize Spaulding as the IRB of record (a highly unique situation). With this approval, it will then be sent to HRPO for the final approval.
- We are in discussions with Nike, USA to partner with us on this project. They will be donating the footwear and insoles that will record patients gait outside of the lab. They are in the process of developing code so that we can access the data from their insole.
- We have recruited, interviewed, hired and on-boarded the Protocol and Data Manager for the project
- We have recruited, interviewed, and hired the Post-doctoral fellow for the project. She is awaiting a delayed visa and should be arriving in early November.
- We have met with the Biomechanics Core to discuss our real-time feedback needs and are continuing these discussions.

External Funding to support Consortium Research

A critical component for sustaining the BADER Consortium research enterprise is the leveraging of Consortium infrastructures for the conduct of externally supported projects.

In the first year of funding, we are pleased to report an initial wave of two external funded projects focused on BADER Consortium gap areas. Externally funded projects of this nature are instrumental to the development and translation of advanced orthopaedic rehabilitation research technologies and will contribute significantly to sustaining BADER Consortium core resources and research activities.

- DARPA

In June of 2012, the University of Delaware was awarded a \$3 million DARPA project through the Center for Composite Materials (CCM). The title of the project is: “Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses (PD-AFO) Designs for Wounded Warriors.” The project goal is to develop an integrated design and manufacturing toolchain to enable rapid prototyping of composite Passive Dynamic – Ankle Foot Orthosis (PD-AFO).

- C-Motion – SBIR

C-Motion, Inc. the Biomechanics Core for the Consortium, was recently awarded a Phase I SBIR from NIH for the development of a low cost real-time biofeedback gait retraining system. The project will further develop the necessary feedback tools to support one of our initial projects, Dr. Davis’ “Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback” research project. As technology development is not allowable with Consortium funds, C-Motion, Inc. applied for SBIR funding to develop this integral technology for ultimate use across the consortium.

Call for Proposals

A primary component of the BADER Consortium is providing funding for orthopaedic rehabilitation research studies. In year 1, an extensive amount of effort was put forth in identifying research gap areas developing the call for proposals.

A primary component of the BADER Consortium is conducting multi-site clinical orthopaedic rehabilitation research studies. In year 1, an extensive amount of effort was put forth by DoD and Consortium leadership towards the identification of research gap areas and development of our limited submission call for research proposals.

Development of research gap areas

In May of this year, we held a strategic planning meeting that included the BADER Consortium Leadership, the MTF representatives and the Research Director of the EACE. Following a review of the EACE research priorities that were developed by EACE through collaboration with the MTFs, each of the MTF representatives then presented a summary of the relevant studies they were conducting at each of their facilities. Discussions then centered around identifying which research gaps best fit the mission of the BADER Consortium, were pivotal to the EACE and would best interface with the present research areas of the MTFs. To avoid overlap in research topics, the team excluded topic areas that are already being well-addressed with other intramural and extramural military funding. Finally, each participant of the meeting casted his/her vote for the top three focus areas and the following research gap areas were identified:

- Community re-integration including development and assessment of health and functional outcome measures of ability to return to work/duty
- Functional outcomes in upper extremity trauma.
- Return to high performance activities following lower extremity trauma.

Development of the Call for Proposals

Once the focus areas for the Call for Proposals were agreed upon, the BADER Consortium leadership worked together to develop the Call for Proposals document, as well as all of the supporting documents and forms that were needed to support the call.

The call for proposals was distributed to all BADER Consortium Affiliates in early September 2012 with full proposals due December 15, 2012. Consortium leadership has received numerous requests for additional information and we are expecting a strong pool of proposals from leaders in academics, industry and medical treatment facilities. We anticipate receiving 5-7 proposals and, depending on costs, funding approximately 50% of those.

Working with the EACE, BADER Consortium leadership will convene annually to discuss current research gaps and priorities. These priorities will be released with the annual call for proposals to be distributed by August 1.

Types of projects supported by BADER Consortium

While large, randomized controlled clinical studies are expected to be part of this consortium effort, multi-site cohort comparison effectiveness studies, innovative systems of care studies, translational studies of technological developments and descriptive clinical pathway(s) evidence-based outcome studies are also appropriate. All studies shall be limited to clinical research and clinical trials that aim to change patient care/patient care pathways and result in increased patient functional outcomes. Animal, drug and technology development studies are excluded from consideration.

Three types of proposal funding models are considered:

- A. Proposals fully supported by BADER Consortium funding and core resources
- B. Proposals supported by a shared combination of BADER Consortium resources and external funding
- C. Proposals that are fully supported by external funds and provide Consortium support to utilize core resources

Partnerships

Partnering with the Extremity Trauma and Amputation Center of Excellence (EACE)

Initiated in 2009, the mission of the Extremity Trauma and Amputation Center of Excellence (EACE) is to serve as the Joint DoD/VA lead organization for policy, direction, and oversight of the multidisciplinary network for continuous care and study of amputations and extremity injuries resulting from trauma, from point of injury thru definitive care and rehabilitation, into lifelong surveillance in order to reduce the disability and optimize the quality of life for Service Members and Veterans (Pendergrass, 2012).

The EACE has a nationwide effect on the care of extremity injuries and amputations. The scope of the organization is complex and highly visible. The EACE programs include Research and Surveillance, Clinical Care, Informatics and Information Management Directorate, and Global Outreach. Pooled expert knowledge in extremity trauma and amputee research is applied in the conduct of studies and management of projects resulting in the development of recommendations having substantial impact on operating programs across three regional CONUS centers, the headquarters, as well as international operations in the private and public sector as well as academia.

The BADER Consortium is actively supporting EACE programs in the following areas:

- On-site staffing (protocol coordination and research support staff) in support of DoD, and in the future, VA research and clinical staff
- Enhanced management and collaboration:
 - Supporting new & evolving research collaboration opportunities with VA and civilian institutions
 - Integration of human resources – staff embedded in treatment centers
 - Enhancing communication & collaboration resources
- Development of DoD/VA sharing opportunities via an enterprise protocol and data management system
- Direct support of clinically relevant research
- Increased external partnerships with civilian organizations and academic institutions
- Expedited publication of research findings to inform clinical practice across the USA and throughout the world

Partnering with industry leaders

Industrial partners play a key role in consortium research activities by developing advanced rehabilitation technologies. The BADER Consortium has established a model system for supporting the translation of these advanced technologies into clinical trials leading to new programs of evidence-based patient care. While several industrial partnerships exist, new partnerships are being formed at a remarkable rate. For example, OttoBock Healthcare and Ossur are the largest providers of orthotic and prosthetic devices in the world. Partnerships also exist with Simbex and C-Motion who are leaders in providing systems and software for analysis of human performance. As the BADER Consortium continues to develop, these partners will play fundamental roles in advancing patient care technologies. The BADER Consortium is currently working with the following industry leaders.

- C-Motion
- iWalk
- Ossur
- Otto Bock Health Care
- Bertec
- Simbex
- Independence Prosthetics and Orthotics

Non-profit partners

While the focus of the BADER Consortium is on orthopaedic rehabilitation research, we have been approached by other external groups to explore opportunities to work together to further support wounded warriors in reaching their maximum capacity and participate in activities of their choosing. To reach maximum capacity, the BADER Consortium must extend beyond traditional rehabilitation research to consider factors related to reintegration, long-term outcomes, and family and community involvement. Therefore, the BADER Consortium has partnered with:

- The Amputee Coalition is the nation's leading organization on limb loss, dedicated to enhancing the quality of life for amputees and their families, improving patient care and preventing limb loss. With the generous support of the public, they are helping amputees live well with limb loss, raising awareness about limb loss prevention and ensuring amputees have a voice in matters affecting their ability to live full, thriving lives.
- The Mid-Atlantic Agrability Project (MAAP) is part of a national program sponsored by the USDA that promotes independence of farmers, watermen, loggers and poultry growers who want to continue to farm despite a disabling or health condition.

Looking Forward

The second year of the BADER Consortium is on track to be highly impactful and successful. We are starting the second year with two research protocols in place. Our limited competition research proposal awards program is well underway and multiple teams are hard at work developing multi-center clinical research proposals for submission to the BADER Consortium Research Advisory Committee. The resulting second wave of multi-site clinical studies will be launched in early 2013.

Our omnibus Cooperative Research and Development Agreement will soon be fully implemented across the consortium. The model omnibus CRADA is being implemented at record pace. Four partner organizations were on-boarded to the CRADA within four weeks. The remaining partners are expected to be on-boarded in the first two months of the second year. Under the MOU with the NIH, the PDMS will be operational providing the Consortium with an enterprise database system to track data, tissue samples and progress across the entire Consortium. Partnerships with the VA, industry and academic institutions continue to emerge to further strengthen the Consortium, as well as building new research teams for future research programs.

The Clinical Research Core (CRC) is the arm of the BADER Consortium that is the center for study management and monitoring and for providing on-site research teams, education and training. Priorities and goals for the CRC are 1) Serve as a unit to support a research-intensive culture in the MTFs and in all present and future Clinical Sites and 2) Institute a uniform and sustainable research infrastructure that will facilitate ongoing and new clinical research protocols across all sites engaged in the research.

BADER Consortium year 2 brings opportunity to finalize the establishment of staffing and training infrastructures. Consortium research support staff will soon be joining medical treatment facilities through the country. Specifically, we will establish a cohesive cohort of CRC staff hired to support research at the four MTFs. This cohort will be responsible for assisting with the design of new study protocols and project applications, modeling of Consortium-wide research protocols into the PDMS, performing data entry and monitoring of all study data, contributing to reporting and analysis of data, and coordinating efforts to secure and maintain the Consortium's Authority to Operate (ATO). Additionally, the CRC will monitor protocol activities and notify the Administrative Core of opportunities to enhance study procedures, training or subject recruitment that require input from the BADER Consortium Coordinating Center. In addition to providing direct support to the MTF researchers, the CRC will also lead efforts to coordinate University course offerings in order to increase the number of highly skilled biomechanics staff at the MTFs as well as future VA partner sites and to assist the University of Delaware's Biomechanics and Movement Science program director with the development of graduate online courses.

The BADER Consortium eagerly anticipates expanding its expert pool of BADER Consortium affiliates, industrial partners, and Government agency collaborations and gathering the Consortium at the first annual BADER Consortium Orthopaedic Rehabilitation meeting.